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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent No:

6,838,089 B1

Issued:

January 4, 2005

Patentees:

Hans Carlsson et al.

Title:

ANTIGEN DELIVERY SYSTEM AND METHOD OF PRODUCTION

Serial No.:

09/308,435

Examiner:

Ginny Allen Portner

Art Unit:

1645

Certificate FEB 0 3 2005

of Correction

CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.8
I hereby certify that this paper is being deposited with the United States Postal Service as first class mail on the date indicated below in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Craig M. Bohlken

Agent Name

PTO Reg. No.

Of 21 2005

Signature

Date of Signature

Certificate of Correction Branch Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

REQUEST FOR CERTIFICATE OF CORRECTION OF PATENT FOR PTO MISTAKE [37 C.F.R. §1.322(a)]

- 1. It is noted that printing errors appear in the referenced patent which are attributable to the Office.
- 2. The exact page and line number(s) where the error(s) is/are shown correctly in the application file is/are:

FEB 0 3 2005

Column and Line Number of Issued Patent	Location in Application File Where the Error is Shown Correctly
Col. 45 Line 54: "schieved" should readachieved	Amendment filed December 4, 2003, page 9, claim 23.
Col. 46 Line 44: "volume of 1:10" should readvolume of 1:100	Amendment filed December 4, 2003, page 11, claim 36.
Col. 48 Line 11: "aced" should readacid	Amendment filed December 4, 2003, page 17, claim 70.

- 3. Patentees request that the issuance of a Certificate of Correction be expedited in accordance with the PTO's policy for expediting issuance of Certificates of Correction, as outlined in the PTO notice, issued August 21, 2002 entitled "Expedited Issuance of Certificates of Correction when the Error is Attributable to the United States Patent and Trademark Office". In support of the requested corrections, Patentees are attaching copies of the relevant pages from the application file with this Request.
- 4. No fee should be due in connection with this communication. However, if a fee is deemed to be due, the Commissioner is authorized to charge such fee to Deposit Account No. 23-1703.

Dated:

0/21/2005

Respectfully submitted,

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Enclosure

UNITED STATES PATENT AND TRADEMARK OFFICE CERTIFICATE OF CORRECTION

PATENT NO. :

U.S. Patent No. 6,838,089 B1

ISSUE DATE :

January 4, 2005

INVENTOR(S):

Hans Carlsson et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In column 45, line 54: "schieved" should read --achieved--.

In column 46, line 44: "volume of 1:10" should read --volume of 1:100--.

In column 48, line 11: "aced" should read --acid--.

MAILING ADDRESS OF SENDER:

PATENT NO. 6,838,089 B1

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Burden Hour Statement: This form is estimated to take 1.0 hour to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box1450, Alexandria, VA 22313.

(Certificate of Correction (PTO/SB/44) [14-3]—page 1 of 1)



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants

Hans Carlsson et al.

Serial No.

09/308,435

Filed

May 19, 1999

For

ANTIGEN DELIVERY SYSTEM AND METHOD OF PRODUCTION (as amended herein)

Examiner

V. Portner

Group Art Unit

1645

I hereby certify that this paper is being facsimile transmitted to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on December 4, 2003.

Richard J.

ner 35,372

PTO Reg. No.

Signature

December 4, 2003
Date of Signature

Attn: Examiner V. Portner

Art Unit: 1645

Number of Pages: 37

FAX NUMBER: 703-872-9306

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

AMENDMENT AND RESPONSE

Sir:

This is submitted in response to the nonfinal Office

Action mailed June 4, 2003 and as a follow-up to the interview

with the Examiner on October 29, 2003. Reconsideration is

- 23. (previously presented) The method of claim 1, wherein the dispersal of the stabilized W/O emulsion in a fluid medium during polymer formulation in step (b) is achieved with a spray drying technique, wherein the stabilized W/O emulsion is dispersed in a gaseous medium to form a spray of W/O emulsion droplets from which said solvent evaporates.
- 24. (previously presented) The method of claim 1, wherein the dispersal of the stabilized W/O emulsion in a fluid medium during polymer particle formulation in step (b) is achieved with a fluid gas technique.
- 25. (previously presented) The method of claim 24, wherein the fluid gas technique is selected from the group consisting of gas anti-solvent precipitation (GAS), solution enhanced dispersion by supercritical fluid (SEDS), precipitation with compressed anti-solvents (PCA), supercritical anti-solvent (SAS) and aerosol solvent extraction system (ASES).
- 26. (previously presented) The method of claim 1, wherein the protein antigen is a *Helicobacter* protein or *Helicobacter* protein fragment.
- 27. (previously presented) The method of claim 26, wherein the Helicobacter protein or Helicobacter protein fragment is from Helicobacter pylori.

- 33. (currently amended) The method of claim 32 1, wherein the matrix polymer is a polyester homopolymer selected from the group consisting of polylactic acid, polyglycolic acid, polyhydroxybutyrate, poly(alpha hydroxyacids) and polycaprolactone.
- 34. (currently amended) The method of claim 32 1, wherein the matrix polymer is a polyester co-polymer selected from the group consisting of poly(lactide-co-glycolide), poly(lactic-co-glycolic acid), poly(hydroxybutyrate-hydroxyvalerate) and poly(lactide-co-caprolactone).
- 35. (original) The method of claim 34, wherein the matrix polymer is poly(D,L-lactide-co-glycolide).
- 36. (previously presented) The method of claim 1, wherein in step (a) the W phase is mixed with the O phase in a ratio by volume of 1:100 to 1:1.
- 37. (currently amended) An antigen vaccine delivery system produced by the method of claim 1, wherein the one or more stabilizing agents is/are a polymer selected from the group consisting of poly(vinyl pyrrolidone), poly(vinyl alcohol), polysaccharides, polyethyleneoxide and water soluble proteins, and wherein the method includes a Double Emulsion (W/O/X) Solvent Evaporation Technique wherein the fluid medium in which the stabilized W/O emulsion is dispersed in step (b) is a liquid phase (X) which is immiscible with the O phase, said

- 69. (new) The method according to claim 52 wherein the protein antigen is a lipidated form of Helicobacter pylori adhesion antigen (HpaA).
- 70. (new) The method according to claim 69 wherein the protein part of the lipidated antigen has an amino acid sequence that is identical to, or substantially similar to, positions 28 to 260 of SEQ ID NO. 2 or 4.
- 71. (new) The method according to claim 59 wherein the protein antigen is a lipidated form of *Helicobacter pylori* adhesion antigen (HpaA).
- 72. (new) The method according to claim 71 wherein the protein part of the lipidated antigen has an amino acid sequence that is identical to, or substantially similar to, positions 28 to 260 of SEQ ID NO. 2 or 4.
- 73. (new) The method according to claim 60 wherein the protein antigen is a lipidated form of *Helicobacter pylori* adhesion antigen (HpaA).
- 74. (new) The method according to claim 73 wherein the protein part of the lipidated antigen has an amino acid sequence that is identical to, or substantially similar to, positions 28 to 260 of SEQ ID NO. 2 or 4.
- 75. (new) The method according to claim 1 wherein the organic solvent in the organic phase (O) is selected from the group